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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. ^{VB}
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EXAMINER

ART UNIT	PAPER NUMBER
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8

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/326,244

Applicant(s)
HOCHMAN, D.

Examiner
Marjorie Moran

Group Art Unit
1631



☒ Responsive to communication(s) filed on Apr 7, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 1 and 12-16 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

☒ Claim(s) 2-11 and 17 is/are rejected.

☒ Claim(s) 2-11 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a method of assessing the physiological condition of a biological material, classified in class 435, subclass 29.
- II. Claims 12-16, drawn to a system (device) for assessing the physiological condition of a biological material, classified in class 422, subclass 55.
- III. Claims 2-11 and 17, drawn to a method for identifying optical contrast enhancing agents, classified in class 356, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Invention II is related to Inventions I and III as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the system of Group II may be used in different processes of use, as exemplified by the methods of Groups I and III.

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Inventions I and III are not related. While the method steps recited in the claim(s) of each Group are similar, the methods are drawn to different results. A method of assessing the physiological condition of a sample may be performed without any reference to or knowledge of optical contrast enhancing agents, or may be performed with known optical contrast enhancing agents, such that the method of Group III is not necessary for the performance of the method of Group I. Likewise, a method of identifying optical contrast enhancing agents may be performed without any reference to the method of assessing the physiological sample of Group I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group II is not required for either of Groups I or III, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ann Speckman on 4/2/00 a provisional election was made with traverse to prosecute the invention of Invention III, claim 17. Subsequently, claims 2-11 were amended to depend from claim 17, therefore claims 2-11 and 17 are considered elected. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 and 12-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

An action on the merits of elected claims 2-11 and 17 follows.

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Claim Objections

Claims 2-11 are objected to because of the following informalities: Each claim should begin with the term --The--. In claim 7, the term --and-- should be inserted before "oncogen" in line 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a step of identifying an optical contrast enhancing agent. Claim 17 recites a method for identifying optical contrast agents in the preamble in line 1, then recites various steps including acquiring test data and comparing acquired test data to comparison data, but fails to recite an identification step and/or a step of correlating acquired test data or comparison results with identification of an optical contrast agent. For these reasons, claim 17 is indefinite.

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Claim 2 recites the term "predetermined" in line 2, with regard to spatial locations. The term is not defined by the specification or in the claims, and no step of determining spatial locations is recited in the claims, therefore it is unclear what is meant by "predetermined" spatial locations. This rejection may be overcome by replacing the term "predetermined" with --selected-- in line 2.

Claim 4 recites the phrase "the one or more geometrical properties" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, therefore the claim is indefinite. It is noted that parent claim 17 recites "one or more optical properties", therefore this rejection may be overcome by replacing "geometrical" with --optical-- in line 2, if such an amendment is commensurate with applicant's intent.

Claim 5 recites the phrase "the one or more properties" in line 2. It is unclear which properties are intended by this phrase (i.e. the geometrical properties of claim 4 or the optical properties of claim 17), therefore the claim is indefinite. This rejection may be overcome by inserting --optical-- before "properties" in line 2.

For purposes of applying the prior art, claims 4 and 5 will be treated as if they recited optical properties.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 2, 4-5, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by HAGLUND *et al.* (AS).

HAGLUND teaches a method of identifying an optical contrast enhancing agent (optical enhancer) suitable for use in imaging (enhancing optical detection) of a tumor (i.e. biological material) wherein an intact organism is exposed to the candidate optical enhancer (i.e. ICG), images of brain are taken before (control data) and after exposure to the optical enhancer (test data acquired), then the "before" and "after" images are compared (pp. 309-310: Enhanced optical imaging technique) in order to assess changes in the brain with regard to optical changes over time, thereby anticipating claims 17, 4-5, and 11. HAGLUND teaches that images may be acquired from different brain areas (i.e. selected spatial locations: P. 310: Figure 2), thereby anticipating claim 2. The optical property measured by HAGLUND in his method is reflection (p. 309), thereby anticipating claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 17, 2-5, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAGLUND *et al.* (AS) in view of HOCHMAN *et al.* (AD).

Claim 17 recites a method of identifying optical contrast enhancing agents suitable for use in enhancing the optical detection of a biological material wherein a cell culture system, a tissue culture system, an organ culture system, or an intact organism is maintained as a sample population, the sample population is exposed to a candidate optical contrast enhancing agent, test data relating to optical properties of the sample population is acquired, and the test data compared to comparison data. Claim 2 limits the method of claim 17 to further comprise acquiring multiple data sets from multiple selected spatial locations in the sample population. Claim 3 limits the method to one wherein the sample population is exposed to a physiological challenge prior to acquiring the test data. Claim 4 limits the method to one wherein control data is acquired prior to exposing the sample population to the candidate optical enhancer. Claim 5 limits the method to one wherein the test data is compared to the control data of claim 4. Claim 7 limits the physiological challenge of claim 3 to one from a selected group. Claim 9 limits the optical properties of the method. Claim 11 limits the sample population to an intact, viable organism.

HAGLUND teaches a method of identifying an optical contrast enhancing agent (optical enhancer) suitable for use in enhancing the optical detection of a biological material, specifically for imaging brain tissue in live human patients, as set forth above. HAGLUND does not teach exposing his patients to a physiological challenge prior to acquiring test data in his method.

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HOCHMAN teaches a method of imaging brain in live human patients wherein he stimulates nerves after acquiring control data but before administering a dye and acquiring test data images (col. 6, lines 16-41).

It would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated the nerve stimulating of HOCHMAN into the method of HAGLUND before acquisition of test images where the motivation would have been to facilitate removal of tumor tissue while minimizing damage to nerve tissue, as taught by HOCHMAN (col. 6, lines 16-20). One skilled in the art would reasonably have expected success in combining the method steps of HAGLUND and HOCHMAN because both teach similar methods of visualizing tumor tissue in brains.

Claims 17 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over VERKMAN *et al.* (CR).

Applicant claims a method of identifying an optical contrast enhancing agent suitable for use in enhancing the optical detection of a biological material, as set forth above. Claim 6 limits the comparison data of claim 17 to be derived from empirically determined controls. Claim 8 limits the method to further comprise maintenance of multiple sample populations in an *in vitro* culture system. Claim 10 limits the sample population to a cell culture system.

VERKMAN teaches a method of selecting (identifying) optical enhancers (dyes; e.g. SPQ derivatives) suitable for use in enhancing optical detection of various properties of cells in cell

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culture systems and intact animals (p. 100, first paragraph, and p. 106, right column).

VERKMAN teaches that his cells can be exposed to (loaded with) dye and fluorescence (test data relating to an optical property) measured over time (p. 106, left column), thus suggesting comparison of test data at later time points to "comparison data" from earlier time points .

VERKMAN further teaches that empirical data can be gathered before test measurements are taken, and teaches that sample populations may be exposed to test agents (i.e. inhibitors and activators) prior to collecting test data (p. 100, first paragraph). VERKMAN teaches that optical properties which may be measured in his method are light scattering, internal reflection (p. 101, Figure 1), or refraction (p. 103, left column). VERKMAN also teaches that multiple sample populations may be used in his methods, including cells in culture (p. 106, left column), thus suggesting multiple sample populations in *in vitro* culture. VERKMAN does not specifically teach a method of identifying an optical enhancer by comparing test data to comparison or control data.

It would have been obvious to one of ordinary skill in the art at the time of invention to have compared the test data of cells loaded with a fluorescent marker (optical enhancer) in the method of VERKMAN to control data (of unloaded cells or cells loaded with different markers), as suggested by VERKMAN, in order to determine if a particular enhancer is cell impermeant and/or a better marker for ion transport, as taught and suggested by VERKMAN (pp. 105-106).

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Conclusion

Claims 2-11 and 17 are rejected; claims 2-11 are also objected to. Claims 1 and 12-16 are withdrawn.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, a supervisory examiner, Michael Woodward, can be reached at (703) 308-4028. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 receptionist whose telephone number is (703) 308-1235.

Marjorie

Marjorie A. Moran
Patent Examiner
Art Unit 1631

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